

REMARKS

Claims 1-35 are pending in this application, with claims 6, 8, 12, 14-20, 23, and 24 having been withdrawn from consideration. Claims 1, 25, and 31 are amended to more clearly define the subject matter. Claim 10 is amended to make a correction in claim dependency and to use a claim term having a proper antecedent basis.

Support for the amendment to claim 1 can be found in the specification, *inter alia*, in original claim 34 and at ¶ [0024]. Support for the amendment to claim 25 can be found in the specification, *inter alia*, at ¶ [0040] and FIG. 11. Support for the amendment to claim 31 can be found in the specification, *inter alia*, at ¶¶ [0032]-[0033] and FIG. 8.

ELECTION OF SPECIES

Applicants acknowledge that the election of species requirement is made final. However, Applicants respectfully note that the Examiner's search has uncovered a reference that allegedly discloses medical implants having therapeutic agents and polymers (see Office Action 01/31/2007, page 6, first full paragraph), which are subject matter areas that were deemed to be separate species requiring additional searches. Applicants continue to believe that a search encompassing all the claims could be made without serious burden to the Examiner, and as such, Applicants respectfully request that the election of species requirement be withdrawn.

DRAWINGS AND SPECIFICATION

The specification is amended to identify the structure referred to by reference number 111 in FIG. 11 and to correct a typographical error in one of the reference numbers.

REJECTIONS UNDER § 112

Claim 25 was rejected as being non-compliant with the definiteness requirement of § 112, second paragraph. As amended, claim 25 now specifies that the medical implant is an expandable

stent. When an expandable stent is expanded, different parts of the stent become deformed to varying degrees, depending upon the particular design of the stent. By observing how different parts of the stent undergo deformation, a person of ordinary skill in the art can readily identify regions of the stent that experience high and low strains.

Therefore, in the context of an expandable stent, the claim terms “regions of high strain” and “regions of relatively lower strain” would be clear and unambiguous to a person of ordinary skill in the art. For at least these reasons, Applicants respectfully submit that claim 25 is now in compliance with the definiteness requirement of § 112, second paragraph, and request the allowance of this claim.

REJECTIONS UNDER § 102

A. Claims 1-5, 7, 9-11, 13, 21, 22, and 25-30

Claims 1-5, 9, 11, 27, and 30 were rejected under § 102(e) as being anticipated by *Noda* (U.S. Patent No. 6,534,197). Claims 1-5, 9, 11, 13, 25, 26, and 30 were rejected under § 102(b) as being anticipated by *Alt* (U.S. Patent No. 6,217,607). Claims 1-5, 9, 10, 13, 25, and 30 were rejected under § 102(b) as being anticipated by *Davidson* (U.S. Patent No. 5,690,670). Applicants respectfully request reconsideration of these rejections.

Independent claim 1 recites a medical implant, in which a first surface is “covered with a filter, wherein the filter covers or contains a catalyst.” An example of a filter covering a catalyst is demonstrated in the embodiment shown in FIG. 1 and described in ¶¶ [0016]-[0017] of the present application. A catalytic layer 15 is disposed over an implant 16. A meso-porous layer 14 is disposed over catalytic layer 15. Meso-porous layer 14 functions as a filter by permitting the flow of fluid into catalytic layer 15, while preventing the entry of particles and other materials, such as blood cells. An example of a filter containing a catalyst is demonstrated in the embodiment shown in FIG. 2 and described in ¶ [0024] of the present application. A meso-porous layer 24 is disposed over an implant 26, and catalysts 25 are contained within the meso-porous layer 24.

Noda describes an implant having three coating layers: a first coating layer on the surface of a substrate, then a metallic layer, and then a second coating layer as the outermost layer (see

Abstract). None of these layers are described to function as a filter. The first coating layer has the “function of shielding against the heat generated during thermal spraying” and serving as a “bonding layer between the metallic layer and the ceramic substrate” (see col. 2, lns. 61-66). The metallic layer and the second coating layer are designed to allow for the ingrowth of bone tissue (see col. 6, lns. 56-58; col. 7, lns. 46-47), and thus, perform a function that is contrary to that of a filter.

Alt describes a stent having three different layers: an innermost tubular core, an intermediate layer, and an outermost layer (see col. 4, lns. 29-35). The outermost layer is made of a ceramic-like material such as iridium oxide (see col. 4, lns. 13-14), which can have catalytic properties (see col. 10, lns. 10-24). However, there is no filter covering the iridium oxide layer.

Davidson describes medical implants fabricated from low modulus Ti-Nb-Zr alloys (see Abstract). The surface of the implant may be treated by an oxygen diffusion hardening process to create an oxide film (e.g., titanium oxide) on the implant (see col. 6, ln. 61 – col. 7, ln. 11). However, *Davidson* contains no description of a filter covering or containing a catalyst.

Thus, none of these references describe a surface that is “covered with a filter, wherein the filter covers or contains a catalyst,” as required by claim 1. For at least these reasons, Applicants respectfully submit that claims 1-5, 7, 9-11, 13, 21, 22, and 25-30 are not anticipated by *Noda*, *Alt*, or *Davidson* and request the allowance of these claims.

B. Claims 31-33

Claims 31-33 were rejected under § 102(b) as being anticipated by *Kula* (U.S. Patent No. 6,325,825). Applicants respectfully request reconsideration of these rejections.

Independent claim 31 recites a medical implant with “a first strut having a tapered transverse cross-section.” An example of a strut having a tapered transverse cross-section is demonstrated in the embodiment shown in FIG. 8, which is a transverse cross-section view of the stent in FIG. 7. FIG. 8 shows that the cross-section profile of stent strut 81 becomes tapered in an outward radial direction.

Kula describes a stent having variable wall thickness (see col. 7, lns. 12-14). However, these variations in wall thickness occur along a longitudinal cross-section of the stent, not a transverse cross-section. For example, the stent can be thicker at the ends than in the middle (see col. 7, lns. 43-45 and FIG. 9) or thinner at the bridges (see col. 7, lns. 46-47 and FIG. 11). In either case, the wall thickness in a transverse cross-section does not vary.

Thus, the stent struts in *Kula* do not have a tapered transverse cross-section, as required by claim 31. For at least these reasons, Applicants respectfully submit that claims 31-33 are not anticipated by *Kula* and request the allowance of these claims.

REJECTIONS UNDER § 103

A. Claim 21, 22, 28, and 29

Claims 21, 22, 28, and 29 were rejected under § 103(a) as being unpatentable over *Alt* in view of *Smalley* (U.S. Patent Appln. Pub. No. 2002/0085968). Applicants respectfully submit that there is no basis for combining *Alt* with *Smalley* in the manner suggested by the Office Action.

Smalley describes methods of making single-walled nanotubes as well as various types of structures (e.g., ropes, fibers, bucky paper) using single-walled nanotubes. The carbon nanotubes may be enclosed in a polymer matrix (see ¶¶ [0257]-[0260] on page 21). As explained above, *Alt* describes a stent having three different layers, with the outermost layer “being a ceramic-like material with a relatively rough external surface” (see col. 4, lns. 13-15). The outer layer may be made of iridium oxide or titanium nitrate.

The Office Action suggests that the bucky paper and polymer matrix described in *Smalley* be used to replace the ceramic-like outer layer or to cover the stent in *Alt*. However, there is no teaching, suggestion, or motivation in either reference for replacing the ceramic-like outer layer with another type of material. In fact, this modification would interfere with one of the features of the *Alt* stent. The ceramic-like outer layer in *Alt* provides a rough surface that “serves to increase the coefficient of friction [sic] and the retention force of the stent when mounted on a balloon for implantation” (see col. 9, lns. 49-52). There is nothing in *Smalley* indicating that the bucky paper

and polymer matrix can provide the surface roughness necessary for retaining the stent on a balloon.

There is also no teaching, suggestion, or motivation in either reference for covering the *Alt* stent with the bucky paper and polymer matrix. In fact, this modification would interfere with one of the features of the *Alt* stent. The ceramic-like material in the outer layer “serves a primary purpose of avoiding tissue irritation and thrombus formation” (see col. 7, lns. 49-51). The outer layer of the *Alt* stent would not be able to serve this purpose if the stent were to be covered with bucky paper and a polymer matrix.

Thus, there is no motivation for using the bucky paper and polymer matrix of *Smalley* to replace the outer layer or to cover the stent in *Alt*. For at least these reasons, Applicants respectfully submit that the combination of *Alt* with *Smalley* is improper.

B. Claims 34 and 35

Claims 34 and 35 were rejected under § 103(a) as being unpatentable over *Kula* in view of *Alt*. Applicants respectfully request reconsideration of these rejections.

1. The Combination of *Kula* with *Alt* is Improper

The Office Action suggests that the stent in *Kula* could be modified to have the outer coating layer of *Alt*. Applicants respectfully submit that there is no basis for combining *Kula* with *Alt* in this manner.

Kula provides a stent with “reduced friction” so that it can “navigate vessels in the body” (see col. 5, lns. 4-6). For example, selective electropolishing of the stent surface can “protect the artery and any plaque from abrasion that may be caused by the stent 10 ends during insertion of the stent 10” (see col. 4, lns. 60-64).

As explained above, the outer layer of *Alt* has a roughness that “serves to increase the coefficient of friction [*sic*] and the retention force of the stent when mounted on a balloon for implantation” (see col. 9, lns. 49-52). Applying this rough layer over the *Kula* stent would increase friction, instead of reducing friction, and may interfere with the ability of the stent to “navigate

vessels in the body.” Therefore, there is no motivation for the modification suggested by the Office Action. For at least these reasons, Applicants respectfully submit that the combination of *Kula* with *Alt* is improper.

2. The Combination of *Kula* with *Alt* Does Not Include All Required Elements

Claims 34 and 35 are dependent from claim 31, which recites a medical implant with “a first strut having a tapered transverse cross-section.” To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *See* MPEP § 2143.03. Even if *Kula* and *Alt* could be properly combined, the combination would not include all the required elements in claims 34 and 35.

As explained above, the *Kula* stent does not have a tapered transverse cross-section. *Alt* is silent about the cross-section profile of its stents and as such, *Alt* does not cure the deficiencies of *Kula*. Therefore, even if *Kula* and *Alt* could properly be combined in the manner suggested by the Office Action, the combination would still not include all the required elements of claims 34 and 35. For at least these reasons, Applicants respectfully submit that claims 34 and 35 are patentable over *Kula* and *Alt*, and request the allowance of these claims.

CONCLUSION

Applicants respectfully submit that the present application is in condition for allowance. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of this application.

The Commissioner is authorized to charge all required fees, fees under § 1.17, or all required extension of time fees, or to credit any overpayment to Deposit Account No. 11-0600 (Kenyon & Kenyon LLP).

Respectfully submitted,

Date: April 24, 2007

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